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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KAREN JOY WEDEKIND and CLAIDIA ANN KIRK

Appeal 2016-004106
Application 12/307,425
Technology Center 1600

Before, DEMETRA J. MILLS, ERIC B. GRIMES, and RICHARD J. SMITH, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

WE AFFIRM.

STATEMENT OF CASE

According to the Specification, page 1, "This invention relates generally to compositions and methods for preventing or treating cardiovascular diseases and particularly to compositions and methods for preventing or treating cardiovascular diseases in felines with hyperthyroidism."

The following claim is representative.

1. A method for treating a cardiovascular disease in a feline with hyperthyroidism and in need of said treating comprising feeding the feline a composition that comprises

from about 0.07 to less than about 1 mg/kg iodine on a dry matter basis

from about 0.1 to about 1.3 mg/kg selenium on a dry matter basis

from about 31 to about 35% protein on a dry matter basis wherein the protein comprises at least about 75% vegetable protein

wherein the feeding step is implemented until a statistically significant improvement is obtained in the measurements for interventricular septum, left ventricular end dimension and left ventricular posterior wall.

Grounds of Rejection

Claims 1–3, 5, 6, 8–15, 29–32, and 34–38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over WO 2004/112499 (cited by Appellant as Wedekind (hereinafter either Wedekind or WO '499) in view of The Cat Clinic of Roswell, Allen, Feline Advisory Bureau, Liu et al. and Remington's.

FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Final Action at pages 2–15.

Cited References

Wedekind WO 2004/112499 A1 Dec. 24, 2004

Liu et al., "Hypertrophic cardiomyopathy and hyperthyroidism in the cat," JAVMA, Vol. 185 No. 1, pp. 52–57 (1984).

Remington's Pharmaceutical Sciences, 17th Ed., pp. 141, 1772-1773, 1786, 1794, Alfonso Gennaro, ed., Mack Publishing Co. (1985).

The Cat Clinic of Roswell, "Feline Cardiomyopathy," (2002).

Allen, Echocardiography as a Research and Clinical Tool in Vetrinary Medicine, Can. Vet. J., Vol. 23, pp. 313–316 (1982).

Feline Advisory Bureau, "Hyperthyroidism in Cats," (2004).

PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

"It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re*

Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990). "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol Myers Squibb v. Ben-Venue Laboratories*, 246 F.3d 1368 (Fed. Cir. 2001).

> If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of the limitations, and the preamble offers no distinct definition of the claimed invention's limitations, but merely states, for example, the purpose or the intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999).

"Where … a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

Obviousness Rejection

The Examiner finds that Wedekind teaches "a reduced-selenium and reduced-iodine packaged feline diet composition, which comprises selenium in an amount equal or less than about 0.65 mg/kg on a dry weight basis and iodine in an amount equal or less than about 1 mg/kg on a dry weight basis, that nutrients can be provided in a form of cat food." Ans. 2. In addition, Wedekind discloses "a cat food containing 0-5% animal protein, 30-35% vegetable protein, 0.2 mg/kg selenium and 0.2 mg/kg iodine on a dry matter basis which is used to treat hyperthyroidism in cats resulting in significant

decreases in levels of thyroid hormones, T3 and T4 (Paragraphs 0005–0008, 0020, 0021, 0034–0042)." Ans. 3.

The Cat Clinic of Roswell discloses

> that hypertrophic cardiomyopathy exhibits increased cardiac muscle mass and decreased space in the ventricular chambers, … that hyperthyroidism can cause cardiomyopathy, that treatment of hyperthyroidism can result in the improvement or reversal of the heart disease and that treatment of the hyperthyroidism can be combined with treatment with diuretics, beta blockers, calcium channel blockers and ACE inhibitors for treatment of the heart disease and that specific diets can be used for the pet's condition (pages 1–3).

Ans. 3. Feline Advisory Bureau discloses that

> cats with hyperthyroidism are also predisposed to development of hypertrophic cardiomyopathy which may require additional treatment but once the underlying hyperthyroidism has been controlled the hypertrophic cardiomyopathy will usually improve or even resolve completely and that treatment includes anti-thyroid drug therapy for reducing the levels of thyroid hormone (Pages 1, 2).

Ans. 3–4.

The Examiner concludes that

> one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that treatment of the hyperthyroidism with the composition of WO '499 [Wedekind] would treat cardiovascular diseases caused by said hyperthyroidism, including cardiac hypertrophy and hypertrophic cardiomyopathy, as treatment of the underlying hyperthyroidism would reduce the excessive amount of thyroid hormones resulting in eventual reversal of said cardiovascular diseases…

Ans. 6–7.

Appellants contend that

> Treatment of hyperthyroidism cannot be construed as or deemed to be equivalent to Appellants' claimed methods for treatment of cardiovascular disease since the art actually teaches not only that cardiovascular disease can develop in non-hyperthyroid felines but also that hyperthyroidism does not necessarily and inevitably lead to cardiovascular disease. Moreover, Appellants also submit that there was nothing in that art that suggested that Appellants' presently claimed compositions would be useful for the treatment of cardiovascular disease in a feline with hyperthyroidism.

Br. 4. Appellants further argue that

> The present invention clearly demonstrates that the recited food compositions (see, e.g. food compositions A to C in paragraph [0063] to [0066]) significantly improve cardiac function as indicated by the ultrasound measurements of intraventricular hypertrophy, left ventricular posterior wall hypertrophy, and left ventricular diastolic diameter (see Table 4). Thyroid function is also advantageously improved with these compositions (Table 4). In contrast, none of the cited art documents provide any data relating to cardiac parameters, and moreover, none of those references provide any indication of the effects of iodine and selenium, in combination with vegetable protein on cardiac function in felines with hyperthyroidism.

Br. 5. Appellants argue that, "'499 [Wedekind] suggests that administration of the diet of paragraph [0035] for an extended period of time has no significant effect on cardiovascular function." Br. 6.

ANALYSIS

We agree with the Examiner's fact finding, statement of the rejection and responses to Appellants' arguments as set forth in the Answer. We find that the Examiner has provided evidence to support a prima facie case of obviousness. Appellants do not argue any individual claims separately, thus

we select claim 1 as representative claim. Arguments not made are waived. We provide the following additional comment to the Examiner's argument set forth in the Final Rejection and Answer.

Appellants argue that they

> have discovered an approach to the prevention and/or treatment of cardiovascular disease in hyperthyroid cats in which the cardiac improvement is not simply ancillary to treatment of hyperthyroidism, a result that is surprising and unexpected to those of ordinary skill in the art. Appellants' discovery is particularly relevant since it is clear that hyperthyroidism and cardiovascular disease can occur independently of one another and each can occur in the absence of the other.

Br. 4. While Appellants argue that the cardiac improvement is not simply ancillary to treatment of hyperthyroidism (Br. 4), that is not the scope of pending claim 1. While cardiovascular disease can develop in non-hyperthyroid felines, the treatment of cardiovascular disease in non-hyperthyroid felines is not within the scope of the pending claims, which describe treatment of a cardiovascular disease in a feline with hyperthyroidism.

Claim 1 entails a single method step of: feeding a feline with hyperthyroidism, a composition that comprises: from about 0.07 to less than about 1 mg/kg iodine on a dry matter basis, from about 0.1 to about 1.3 mg/kg selenium on a dry matter basis, from about 31 to about 35% protein on a dry matter basis wherein the protein comprises at least about 75% vegetable protein. Wedekind discloses a similar feed composition (Ans. 2-3) and method step (Example 1, p. 13). Wedekind discloses that treatment with low selenium, low iodine feed resolves hyperthyroidism and results in

T3 and T4 levels in the normal range (Table 5, ¶ 42). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 919 F.2d at 1578. If a reference discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of the reference's disclosure. *Compare*, *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1379 (Fed. Cir. 2005).

Furthermore, the Examiner establishes that it is well known in the art from the *Cat Clinic of Roswell* that, "[h]yperthyroidism is the most treatable cause of cardiomyopathy [in felines] since complete resolution of the heart disease is possible if diagnosed and treated early." P. 2. Similarly, the *Feline Advisory Board* discloses that cats with hyperthyroidism are predisposed to hypertrophic cardiomyopathy. P. 1.

Feline Advisory Board establishes that resolution of hypertrophic cardiomyopathy is a known, concomitant benefit of treatment of hyperthyroidism in felines. "[O]nce the underlying hyperthyroidism has been controlled the hypertrophic cardiomyopathy will usually also improve, or even resolve completely." P. 1. Thus, one of ordinary skill in the art at the time of the invention would have expected that treatment of hyperthyroidism in felines and reducing thyroid hormone levels to normal with a feed as disclosed in Wedekind, would provide a concomitant benefit

of resolution of cardiovascular disease, including hypertrophic cardiomyopathy.[1]

Finally, Appellants argue that the feline feed compositions used in the claimed method "significantly improve cardiac function" (Br. 5). Appellants provide no comparative evidence with the closest prior art feed compositions of Wedekind to support unexpected results.

The obviousness rejection is affirmed for the reasons of record.

CONCLUSION OF LAW

The cited references support the Examiner's obviousness rejections, which are affirmed for the reasons of record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

[1] We remind Appellants that the pending rejection is an obviousness rejection, and thus not controlled by the anticipation rejection facts of *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005).